2413 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-0703
(202) 225-3661

59 ELM STREET
SECOND FLOOR
NEW HAVEN, CT 06510
(203) 562-3718

DURHAM/MIDDLEFIELD/MIDDLETOWN
(860) 344-1159

WEBSITE: HTTP://DELAURO.HOUSE.GOV

UNITED STATES
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October 9, 2015

Dr. Stephen Ostroff, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee Regarding the Essure Female Sterilization Device

Dear Acting Commissioner Ostroff:

I am deeply disturbed by reports from women about the severe adverse health effects they have suffered due to implantation of Bayer HealthCare's Essure System for permanent female sterilization. There are now more than 5,000 adverse events reports filed by doctors and patients about Essure to the Food and Drug Administration (FDA) describing negative side effects. Those reports include four adult deaths related to the device five fetal deaths that occurred in women who became pregnant following placement of Essure. In addition, women have reported debilitating pain or menstrual cycles, device migration and breakage, chronic immunological problems, numerous pregnancies and miscarriages in women who became pregnant following placement of Essure, and other serious adverse effects caused by the device. A citizen petition filed on behalf of hundreds of women injured by Essure asks FDA to remove the device from the market. FDA should take immediate action to do so.

On September 24, 2015, the FDA's Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee held a meeting to discuss the risks and benefits of the Essure System. During the public comment period at the meeting, Essure patients, consumer advocates, and medical professionals questioned the safety and effectiveness of Essure, and the integrity of the data provided to the FDA and the public. Many called on FDA to withdraw its approval for Essure.

In addition, a study by researchers at Yale School of Medicine published in April 2014 concluded that tubal ligation is more effective than Essure. Because of the problems regarding proper placement and occlusion, the cumulative pregnancy risk for Essure is 96 per 1,000 at 10 years, which is 3-4 times the risk after tubal ligation (24-30 per 1,000). Given Essure's high pregnancy rate compared to other available procedures, this device should not be touted as a wonder birth control solution. And yet, the FDA-approved patient booklet states "the Essure procedure is 99.83% effective" without clearly explaining the numerous caveats that result in a much lower success rate.

There were three postapproval studies ordered regarding Essure, two in 2002 and one in 2004. Yet there is strong reason to believe that data presented to FDA did not include the full breath of side effects reported by women. For example, the manufacturer chose not to report severity of pain systematically in the post-approval studies, and pain outside the pelvis (including abdominal pain and low back pain) was not reported at all. Chronic pain was made to appear non-existent by reporting only on "persistent" pain, defined as pain recorded at every follow-up visit. This definition was too rigid to capture many patients with chronic, recurring pain. Finally, patients involved in the clinical trials have complained that their symptoms were not accurately and consistently reported, including severe, chronic pain. At least one patient has presented FDA with written evidence documenting that answers were crossed out and changed in her study records. Given this background, it appears that Conceptus, Essure's prior manufacturer, systematically grossly underreported symptoms experienced by patients treated with the device. Moreover, adverse event reports submitted by patients clearly demonstrate that these devices have severely harmed many women.

Given these concerns, I request answers to the following questions:

1. Why was the Advisory Committee not given the opportunity to hear from a panel of women who had participated in the clinical trials and who reported to the FDA that data the Essure sponsors provided to the FDA, including patients' age and their complications, were changed by the sponsor? Why weren't any of the women in the Essure clinical trials who had these experiences *invited* to speak at the public meeting? Instead, women were only able to speak during the public comment period and they were limited to only three minutes. Bayer officials were given the opportunity to refute the women's statements; however, the women were not given an opportunity to respond to Bayer's remarks.

2. Why didn't FDA seek the input of independent experts such as Dr. Gariepy at Yale School of Medicine about their research on Essure? Dr. Gariepy traveled to the meeting at her own expense, but like the patients, was given only three minutes to speak from the audience, rather than from a lectern at the front of the room with the other "experts."

3. What has FDA done to follow up with Bayer and obtain additional data on pain and other side effects during the post-market studies? Has FDA requested the full patient-level datasets from these trials so that the agency can conduct its own analyses regarding pain and other symptoms? Or does it continue to rely on summaries and analysis carried out by the company, which may leave out or misrepresent important information?

4. Has FDA requested and reviewed the long-form study records of additional patients in order to determine how widespread under-reporting, inconsistencies, crossed-out answers, and other potential data quality problems were during the Essure clinical trials?

5. To date, FDA has posted only 11 of the more than three thousand comments currently submitted to the docket of the citizen's petition requesting removal of Essure from the market. Why haven't additional comments been posted? When will the additional comments be posted? When will FDA act on this petition?

Essure's benefits do not outweigh its risks, and it should be withdrawn from the market. If well-designed studies in the future indicate that the benefits outweigh the risks compared to alternative permanent or long-term contraception, the FDA can consider approving Essure at that time.

I look forward to receiving your response and urge and FDA to take immediate action on this matter.

Sincerely,

Rosa L. DeLauro

Rosa L. DeLauro
Member of Congress